CRITERIA FOR PRIOR AUTHORIZATION

Alpha Interferon

PROVIDER GROUP Pharmacy
Professional

MANUAL GUIDELINES The following drug requires prior authorization:
Peginterferon alfa-2b (PegIntron®)

CRITERIA FOR INITIAL APPROVAL FOR CHRONIC HEPATITIS C (DOES NOT APPLY TO PATIENTS USING TRIPLE THERAPY)

Must meet all of the following:

- Patient must have a diagnosis of chronic hepatitis C
- Must be prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist
- Patient must be 3 years of age or older
- Patient has a detectable hepatitis C viral level (HCV RNA) in the serum
- Patient is positive for HCV antibodies
- Patient must not have decompensated liver disease
- Must be taken in combination with ribavirin unless patient has a contraindication or intolerance to ribavirin
- Patients 18 years of age and older with genotype 1 must be taking PegIntron in combination with a Hepatitis C NS3/4A protease inhibitor unless they have a contraindication or intolerance to Hepatitis C NS3/4A protease inhibitors
- Patient must be identified as one of the following prior to initiation of therapy
    - treatment naïve (no hepatitis C drug treatment in the past)
    - previous partial responder (patient failed to achieve SVR after at least 12 weeks of previous treatment with peginterferon alfa and ribavirin, but demonstrated a ≥2 $\log_{10}$ reduction in HCV RNA by 12 weeks)
    - relapse to previous therapy (patient had undetectable HCV RNA by at least 12 weeks of previous treatment with peginterferon alfa and ribavirin but failed to demonstrate maintenance of SVR following previous treatment)
    - previous null responder (patient had a <2 $\log_{10}$ reduction in HCV RNA at week 12 of previous treatment with peginterferon alfa and ribavirin)
    - cirrhotic patient (patient has cirrhosis of the liver)

LENGTH OF INITIAL APPROVAL 12 weeks

RENEWAL CRITERIA FOR TREATMENT NAÏVE PATIENT ON PEGINTRON/RIBAVIRIN Must meet all of the following:

- Patient must have an undetectable HCV-RNA at week 24
- Patients with genotype 1 may be approved for up to 48 weeks of therapy
- Patients with genotypes 2 and 3 may be approved for up to 24 weeks of therapy

LENGTH OF APPROVAL FOR TREATMENT NAÏVE PATIENT ON PEGINTERON/RIBAVIRIN 12 weeks (up to a total of 48 weeks of therapy)

RENEWAL CRITERIA FOR RETREATMENT WITH PEGINTRON/RIBAVIRIN Must meet all of the following:

- Patient must have an undetectable HCV-RNA at weeks 12 and 24

LENGTH OF APPROVAL FOR RETREATMENT WITH PEGINTERON/RIBAVIRIN 12 weeks (up to a total of 48 weeks of therapy)

RENEWAL CRITERIA FOR PEDIATRIC PATIENT ON PEGINTRON/RIBAVIRIN Must meet all of the following:

- Patients with genotype 1 may be approved for up to 48 weeks of therapy
- Patients with genotypes 2 and 3 may be approved for up to 24 weeks of therapy

LENGTH OF APPROVAL FOR PEDIATRIC PATIENT ON PEGINTERON/RIBAVIRIN 12 weeks (up to a total of 48 weeks of therapy)

RENEWAL CRITERIA FOR PEGINTRON MONOTHERAPY Must meet all of the following:

- Patient must have an undetectable HCV-RNA at week 24

LENGTH OF APPROVAL FOR PEGINTRON MONOTHERAPY 12 weeks (up to a total of 52 weeks of therapy)

IF PATIENT IS USING PEGINTRON FOR TRIPLE THERAPY PROTEASE INHIBITOR CRITERIA MUST BE APPROVED